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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,847	03/30/2001	Peter J. Sims	SCRIP1220-1	7002

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EXAMINER
FOLEY, SHANON A

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1648	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,847	Applicant(s) SIMS ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Inventions 1-6, claims 1-7 and 14-16, drawn to an isolated polynucleotide, classified in class 536, subclass 23.2. Independent inventions 1-6 correspond to SEQ ID NOs: 3, 5, 7, 9, 13, and 15, respectively.

Inventions 7-11, claims 8 and 9, drawn to a purified polypeptide, classified in class 530, subclass 387.9. Inventions 7-12 correspond to SEQ ID NOs: 4, 6, 8, 14, and 16, respectively.

Invention 12, claims 10-12, drawn to antibodies, classified in class 530, subclass 387.9.

Inventions 13-18, claim 13, drawn to a method of making a polypeptide, classified in class 435, subclass 70.1. Inventions 13- correspond to SEQ ID NOs: 4, 6, 8, 10, 14, and 16, respectively.

Invention 19, claims 17-20, drawn to a method of identifying a compound that modulates expression of an enzyme, classified in class 435, subclass 7.71.

Inventions 20-23, claims 21-23, drawn to a transgenic knockout mouse, classified in class 800, subclass 18. Inventions 15-18 correspond to SEQ ID NOs: 9, 11, 13, and 15, respectively.

Invention 24, claims 24 and 25, drawn to a method of making a transgenic mouse, classified in class 800, subclass 25.

Invention 25, claims 26-34, drawn to a method of inhibiting or preventing a viral infection by introduction of a polypeptide, classified in class 424, subclass 185.1.

Invention 26, claims 35-37, drawn to a method of identifying a compound that modulates enzyme activity, classified in class 435, subclass 7.71.

Inventions 27-30, claims 38, 39, 42-48, drawn to a method of treating cancer by administering a compound that modulates enzyme activity, classified in class 424, subclass 184.1. Inventions 22-25 correspond to SEQ ID NOs: 2, 4, 6, and 8, respectively.

Inventions 31-34, claims 38-41 and 43-48, drawn to a method of treating a viral infection by administering a compound that modulates enzyme activity, classified in class 424, subclass 184.1. Inventions 26-29 correspond to SEQ ID NOs: 2, 4, 6, and 8, respectively.

Invention 35, claims 49-51 and 54, drawn to a method of diagnosing cancer, classified in class 424, subclass 9.1.

Invention 36, claims 49, 50, and 52-54, drawn to a method of diagnosing a viral infection, classified in class 424, subclass 9.1.

Inventions 37-44, claims 55-57, drawn to a method of extending the viability of cells, classified in class 435, subclass 69.2. Inventions 32-40 correspond to SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, and 15, respectively.

Invention 45, claim 58, drawn to a method of treating a subject at risk by introducing a polynucleotide encoding a polypeptide, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-6 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different polynucleotides that are structurally dissimilar and encode structurally distinct polypeptides. Therefore, a search for any of the polynucleotides is non-convergent.

Inventions 7-11 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different polypeptides that do not share structural similarities. Therefore, a search for any of the polypeptides is non-convergent.

Inventions 1-6 and 7-11 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case inventions 7-11 do not require the polypeptides of inventions 1-6 to make them and can be made synthetically.

Inventions 1-6, 7-11, and 12 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products are functionally different and have distinctly different structural components, each having separate fields of search.

Inventions 13-18 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different polypeptides that do not share structural similarities. Therefore, a search for any of the polypeptides is non-convergent.

Inventions 7-11 and 13-18 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of inventions 7-11 can be made by chemical synthesis and the method steps can be used to make any structurally distinct product, such as SEQ ID NOs: 4, 6, 8, 10, 14, or 16, respectively.

Inventions 1-6, 7-11 and 13-18 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions drawn to a method of making a polypeptide do not require the products of inventions 1-6 or 7-11 to accomplish the intended goal of the method.

Inventions 1-6 and 19 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions 1-6 can be used in materially different processes, such as extending the viability of mammalian cells or tissues.

Inventions 7-11, 12, 13-18 and 19 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the method of identifying a compound requires the use of a materially different product, a polynucleotide, and does not require polypeptides of inventions 7-11, or the antibodies of invention 12. In addition, the inventions 13-18 are drawn to a materially different process using unrelated ingredients to accomplish different goals.

Inventions 20-23 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different polynucleotides as endogenous genes in a transgenic animal. Therefore, a search for any of the polynucleotides is non-convergent.

Inventions 1-6, 7-11, 12, 13-18, 19 and 20-23 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions 1-6 and 20-23 are distinct because the polynucleotides of inventions 1-6 do not exist in vivo because they are isolated. Furthermore, a mouse is a living organism that is structurally and functionally distinct from inventions drawn to different inanimate products 1-6, 7-11, and 12. In addition, a mouse is not required to make any polypeptide of inventions 13-18 or identifying a compound in invention 19.

Inventions 20-23 and 24 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the transgenic mouse can be made by materially different methods, such as microinjection into an egg for in vitro fertilization.

Inventions 1-6, 7-11, 12, 13-18, 19 and 24 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of making a mouse of invention 24 does not require any of the products of inventions 1-6, 7-11, 12 and requires materially different method steps to accomplish different goals of inventions 13-18 and 19.

Inventions 7-11 and 25 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in materially different processes, such as making antibodies or identifying compounds that inhibit enzyme activity in vitro.

Inventions 1-6, 12, 13-18, 19, 20-23, 24 and 25 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention 25 is patenatbly distinct from inventions 1-6, 12 because the method does requires products that are materially and functionally distinct from the products of inventions 1-6, 12, and 20-23. Furthermore, a method of inhibiting a viral infection requires

different method steps and different ingredients from the methods of inventions 13-18, 19, and 24.

Inventions 7-11 and 26 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions 7-11 can be used in materially different process, such as such as making antibodies, identifying compounds that inhibit enzyme activity in vitro, or inhibiting viral infection.

Inventions 1-6, 12, 13-18, 19, 20-23, 24, 25 and 26 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the method of identifying a compound that modulates enzyme activity does not require any of the products of inventions 1-6, 12, 20-23, and requires different method steps and different ingredients from the methods of inventions 13-18, 19, 24, and 25.

Inventions 1-6, 12, 13-18, 19, 20-23, 24, 25, 26 and 27-30 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention does not require any of the distinct products of inventions 1-6, 7-11, 12, 20-23 and requires different method steps and different ingredients from the methods of inventions 13-18, 19, 24, 25, 26.

Inventions 27-30 and 31-34 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to treating different subjects suffering from unrelated illnesses. Viruses are infectious agents and cancer is not. Therefore, the methods have different goals and can be practiced with materially different compounds. The different amino acid sequences of each invention are structurally distinct.

Inventions 35 and 36 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to accomplishing different goals. One is to diagnose any viral infection and the other is to diagnose cancer. Therefore, the inventions involve different subject populations.

Inventions 37-44 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different inventions can be practiced with structurally distinct products, i.e., SEQ ID NO: 3, 5, 7, 9, 11, 13, or 15.

Inventions 45 and 31-34, 35, 36, 25 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the methods involve administering materially different

ingredients, involve different method steps, and include different subject populations. The subject population of invention 45 are healthy since they are only at risk for developing a disorder, where as the population of 25 is infected or potentially infected with a virus, inventions 31-34 include already infected patients, and the methods of 35 and 36 are drawn to diagnosis, not treatment or prevention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
January 14, 2002

James C. Housel 1/14/02
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